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2861 34th Street South • St. Petersburg, FL 33711
Phone: 727-867-4444 • Fax: 727-866-1438

Theodore L. Drell, Ph.D.
Vice President

February 14, 2005

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Overnight Mail

Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Ref: Almased® Nutritional Supplement

Dear Sir and/or Madam:

This is notification and substantiation to the Food and Drug Administration (FDA) for Dietary Supplement Claims made pursuant to Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act for claims made on the "Almased" product label, a dietary supplement, which went on sale January, 2005. The claims are as follows:

Claim I: "Reduce Weight, inches and Fat"

Claim II: "Revitalize Energy"

Claim III: "Restore Wellness with Almased"

Claim IV: "Protects muscle mass while losing fat"

Claim V: "Additional benefits of probiotics and enzymes aid in digestive and immune system function"

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LET 15756

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Claim VI: "Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of Almased provides 25 grams of soy protein."

The information contained herein is a complete and accurate representation of the product named. Almased USA, Inc. has hereto provided substantiation of these statements of nutritional support based on the scientific literature which render those statements truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "Theodore L. Drell", with a long horizontal flourish extending to the right.

Theodore L. Drell, Ph.D.